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ISMP An ECRI Affiliate

Nurse AdviseERR®

Educating the Healthcare Community About Safe Medication Practices

# Safety committees need to proactively address the risk of accidental cerebral injection of IV drugs

**PROBLEM:** Inadvertent intraventricular administration of medications or contrast media is a rare but serious event caused in large part by the ubiquitous Luer connector that permits misconnections between parenteral syringes/tubing and intraventricular access devices. New neuraxial connectors—NRFit—meeting the International Organization for Standardization (ISO) design changes are beginning to emerge, and medical devices which connect to the neuraxial route will eventually change to the new ISO standard design that will prevent misconnections.[1] However, intraventricular drains and tubing are NOT presently included in the NRFit initiative, enabling conditions prone to inadvertent misconnections, particularly by healthcare practitioners unfamiliar with intraventricular drains. Two months ago, ISMP received such a report involving a postcraniotomy patient who received radiopaque contrast media via an external ventricular drain (EVD) instead of via an appropriate intravenous (IV) route during a magnetic resonance imaging (MRI) study.

## External Ventricular Drain (EVD)

An EVD is a flexible plastic catheter placed in the brain that uses gravity to drain cerebrospinal fluid (CSF) out of the ventricles to an external chamber or bag, which relieves elevated intracranial pressure (ICP) and, when connected to a transducer, allows ICP monitoring. EVDs are typically used to manage: acute symptomatic hydrocephalus caused by a brain tumor, subarachnoid hemorrhage, intracerebral hemorrhage with ventricular extension, and cerebellar stroke; ICP monitoring in traumatic brain injury; and other targeted therapeutic interventions.[2,3] After an EVD catheter is placed in the brain, the distal end, which protrudes from the scalp, is connected to a collection system with tubing, at least one three-way stopcock or manifold, a flushless transducer for ICP monitoring and CSF drainage, and at least one access port (for the occasional administration of antibiotics such as vancomycin directly into the brain). The CSF collection system is mounted on an IV pole.

Epidural tubing is yellow-striped, without access ports, and may have a NRFit connector to prevent tubing or syringe misconnections, whereas the typical EVD collection system has clear rigid tubing (possibly with a thin blue line through the tubing), an access port, and is not available with a NRFit connector. Thus, EVD tubing is similar in appearance to IV tubing and vulnerable to tubing misconnections and wrong route drug administration errors. Also, the three-way stopcock/manifold and port connected to the EVD tubing is often white and the same shape and size as stopcocks/manifolds and ports on common IV tubing.

## Event Report

Prior to surgery, a neurosurgeon placed an EVD in a patient with a brain mass and hydrocephalus. A contrast-enhanced MRI was later ordered for preoperative planning. A nurse from the neurosurgical intensive care unit (ICU) transported the patient to the radiology suite and provided a verbal handoff to a radiology nurse and an MRI technologist. However, the radiology nurse had to leave the MRI suite for an emergency computed tomography (CT) scan for another patient. The MRI technologist who

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## SAFETY wires

**FDA communication on the accuracy of ENFit low dose tip syringes.** ENFit syringes should be used to prepare and administer liquid medications intended for the enteral route to prevent misconnections and the accidental administration of an oral liquid medication via another route. However, a recent US Food and Drug Administration (FDA) communication to patients and healthcare providers (www.ismp.org/ext/798) mentioned the potential for overdoses, under certain conditions, when using ENFit low dose tip (LDT) syringes (between 0.5 mL and 6 mL). This can happen if the user does not clear the moat area around the syringe tip (**Figure 1**) before administering

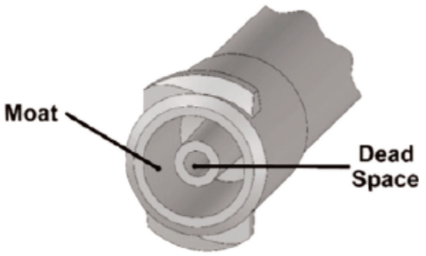


**Figure 1.** Liquid medications that enter the moat area of an ENFit low dose tip (LDT) syringe under certain conditions may lead to an overdose if not cleared.

a medication. Liquid medications can enter the moat area when the syringe is dipped into a liquid medication without using a syringe filling adapter such as an ENFit cap or medication straw. If fluid or air bubbles enter the moat area, the tip of the syringe should be tapped or flicked to eliminate the fluid or air bubbles before administering the medication. ISMP has recommended this practice when a straw or ENFit-compatible bottle cap is not used, which could happen if doses are prepared extemporaneously from a unit dose cup or bottle. ISMP believes that the overdose risk is mainly with oral liquid medications that enter

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received the verbal handoff report was not certified to administer IV contrast, so another MRI technologist came to assist. An incomplete handoff report occurred between the first and second MRI technologists. The ICU nurse remained in the MRI suite but did not repeat the verbal handoff to the second MRI technologist.

Unfortunately, the technologist administering the IV contrast media, gadobutrol (**GADAVIST**), did not adequately confirm with the neurosurgical ICU nurse about which specific line and access port to use to administer the gadobutrol. The technologist was unaware that the patient had an EVD in addition to an upper extremity midline IV access. The technologist mistakenly injected the contrast media into the EVD access port, which he mistook as the IV access port. Although he was an experienced certified radiology technologist, he omitted essential safety steps prior to injecting the contrast media, including tracing the line to the insertion point and aspiration of what the technologist thought was the midline IV access to ensure a blood return.

After the MRI, the patient's mental status deteriorated, and a stat cranial CT scan was performed. The CT scan revealed the presence of radiopaque contrast media in the intraventricular and cisternal system, and it became evident that the gadobutrol had been inadvertently injected into the EVD during the MRI. High doses of gadobutrol intended for cranial MRI contrast can cause severe neurotoxicity.[4] The patient was treated with a **PENT**obarbital infusion to induce a coma and serial EVD lavage with sterile saline. He slowly improved with treatment and supportive care.

## Similar Events in the Literature

Similar events associated with inadvertent intraventricular administration have been published in the literature.[4-8] For example, in 2011, McConnell et al. reported a case of accidental intraventricular administration of phenytoin through an EVD.[5] The patient had been hospitalized with septic shock and a temporal lobe abscess with hydrocephalus. In the neurosurgical ICU, he was started on mechanical ventilation, and an emergency craniotomy was performed with placement of an EVD for CSF drainage. The patient developed acute renal failure requiring renal replacement therapy and transfer to a general ICU. An experienced ICU nurse inadvertently injected 250 mg (25 mL) of phenytoin into the EVD port instead of the venous catheter. In this hospital, although EVDs were relatively common in neurosurgical ICUs, they were rarely seen in general ICUs; thus, unfamiliarity with the EVD was a contributing factor in this event. The error was immediately detected, and the EVD was drained and lavaged. The patient experienced tachycardia, hypertension, and seizure activity. A propofol infusion was used for sedation for 24 hours. After resolution of the renal failure, the patient was returned to the neurosurgical ICU. Fortunately, he recovered slowly and had no permanent adverse effects due to the error.

In 2013, Nayak et al. presented two cases of postoperative inadvertent administration of gadobutrol into an EVD port that was mistaken for IV tubing.[4] In the first case, a patient underwent resection of a meningioma and placement of an EVD for drainage. Several days later, a contrast-enhanced MRI was performed to assess residual tumor mass, which demonstrated profound hyposensitivity throughout the brain's ventricular system and subarachnoid spaces as well as susceptibility artifact along the margins of the ventricles. Shortly after the MRI, the patient became agitated and hypertensive. The following day, he developed aphasia, dysarthria, depressed mentation, right facial drooping, and increased urinary output suggestive of diabetes insipidus. A cranial CT suggested the inadvertent administration of MRI contrast via the EVD. The EVD tubing was mistaken as IV tubing, as it had been hidden underneath the patient's hospital gown, exiting a sleeve on the same side as the patient's antecubital IV line. The contrast media was found in the EVD collection bag, confirming the error. The patient required long-term ventilatory support and medical management of newly developed nonconvulsive status epilepticus.

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the moat area, especially with tiny doses used for pediatric patients.

While the FDA's analysis has identified a potential for overdose using ENFit LDT syringes, no patient injuries have been reported. In contrast, serious patient injuries and deaths have been reported due to misconnections (www.ismp.org/ext/799). Therefore, FDA continues to recommend the use of enteral devices and syringes that reduce the risk of misconnections, including ENFit LDT syringes.

### Trulicity pen should never be primed.

A health system received several reports about wasted **TRULICITY** (dulaglutide) pens because nurses tried to prime them prior to administration. Trulicity, a glucagon-like peptide-1 (GLP-1) receptor agonist, improves glycemic control in adults with type 2 diabetes mellitus, lowering hemoglobin A1c levels. It is available as a single-dose solution pen in 4 strengths. Nurses may not be familiar


**Figure 1.** Trulicity pen has an attached needle at the base and does not need to be primed before administration.

with Trulicity pens since weekly doses are designed for self-administration at home. While nurses are familiar with various types of pens that require priming, the Trulicity "pen" is more like an auto-injector with its own needle that does not require priming. Conversely, some of the other GLP-1 agonist medications, such as **VICTOZA** (liraglutide), **OZEMPIC** (semaglutide), and **BYETTA** (exenatide), require the attachment of a disposable needle and priming.

With the Trulicity pen, nurses should remove the base cap and throw it away, then place the clear base flat and firmly against the skin at the injection site (abdomen, thigh, or upper arm), turn the green bar to unlock the pen, then press and hold the green injection button (www.ismp.org/ext/787) (**Figure 1**). After a click, continue to hold the clear base firmly

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Upon retrospective review of MRI images, a second case was discovered, which occurred 2 years prior.[4] A craniotomy patient with an EVD had a postoperative contrast-enhanced MRI that showed an identical pattern of profound hyposensitivity throughout the ventricular system and subarachnoid spaces and susceptibility artifact along the margins of the ventricles. After the MRI, the patient's mental status became altered, and she suffered severe headaches. Unlike the patient described previously, this patient did not develop status epilepticus, nor did she require long-term ventilatory support. Her neurological status returned to baseline several days after the MRI.

In 2016, Singh et al. reported a case of inadvertent administration of gadolinium contrast through an EVD during an MRI after resection of a meningioma.[6] After the MRI, the patient became hypertensive and complained of nausea and anxiety. By the next morning, the patient developed rapidly progressing aphasia, right facial droop, and delirium. The MRI from the previous day demonstrated extensive cerebral edema, which led to the investigation and discovery of the inadvertent intraventricular administration of contrast media via the EVD. This was later confirmed by the presence of gadolinium in the EVD collection bag. The patient had to be mechanically ventilated, a lumbar drain was placed, and IV dexamethasone, hypertonic saline, norepinephrine, and antiseizure medications were initiated. The patient developed nonconvulsive status epilepticus and continued to deteriorate. He was discharged to a skilled nursing facility with long-term, irreversible disability still present after 2 years.

Other published errors occurred more than a decade ago. In one close call, an EVD tunneled to exit just below a child's clavicle was mistaken for a central venous line, and the child almost received intraventricular propofol and rocuronium during anesthesia induction.[7] In another case, an adult patient received intraventricular etomidate and rocuronium through a ventriculostomy catheter during rapid sequence intubation in an ICU.[8]

**Safe Practice Recommendations:** The issue of medical tubing misconnections has become a global imperative for patient safety with the new ISO medical device connector standards. However, to our knowledge, inadvertent EVD misconnections have yet to be considered within the ISO standards development process. Nevertheless, these strategies can prove effective in reducing the risk of an error, although many rely on individual practice and vigilance.

## EVD Safety Management

**Avoid tunneling near the clavicle or neck.** When placing an EVD, if the catheter exits from any location other than the scalp, avoid subcutaneous tunneling of the EVD to common central venous access sites, including just below the clavicle or near the jugular vein in the neck.[7]

**Affix bright warning labels.** To distinguish EVD tubing from other medical tubing (including IV lines), affix a prominent and colorful label near the distal end of the EVD tubing set-up to communicate that it is a ventricular drain (e.g., CSF drain). Also consider labeling the EVD stopcock or manifold.

**Cap the ports.** McConnell et al. recommend placing caps or some type of covering on every access port that is not intended for IV administration, including EVD ports.[5] The removal of the cap or covering for any injection requires an independent double check of the medication or solution, including the route of administration. Some hospitals also require an independent double check prior to any injection through a stopcock, while others have a policy to never use a stopcock for injecting medications.

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against the skin for about 5-10 seconds until a second click, which happens as the needle starts retracting. Any attempt to "prime" a Trulicity pen by going through these steps and injecting contents into the air would empty its contents and waste the pen.

Trulicity is packaged for patient use in cartons of 4 pens for a 1-month supply. Although the carton includes a fold-out pamphlet with easy-to-understand instructions and sketches, there is only one pamphlet per carton, so it cannot be given to nurses for reference with each dispensed dose. Instead, the health system that reported this problem has designed information leaflets to include for nurses when dispensing Trulicity. Instructions in the package insert or the accompanying pamphlet may also be copied (color copying is preferred since the instructions use color to make them easy to understand). The health system is also adding comments to the medication administration record (MAR) that state, Do Not Prime the Trulicity Pen. This note will appear when the nurse opens the MAR, before administration.

### Drug manufacturers: Stop printing barcodes across round surfaces!

A hospital discovered a billing issue with its rabies immune globulin (human) 2 mL vial, **KEDRAB** (manufactured by Kamada, distributed by Kedrion Biopharma). They were not receiving the product at the correct contracted price because they had "no documented administrations" of it at the hospital. However, the hospital had been ordering the product frequently, so it clearly was being used. The pharmacy researched the problem and found numerous instances of not billing for the medication. It turned out that the medication was not being charted as being given on the medication administration record (MAR). Although nurses had scanned the barcode on the product label, documentation of administration failed because the barcode on the product is printed on the label horizontally, on the curvature of the round vial (**Figure 1**, page 4), rendering it unreadable by the laser scanner.

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**Placement on different sides.** Equipment for EVDs and pumps for venous lines should be placed on separate IV poles and, when possible, maintained on opposite sides of the patient's bed.

**Avoid threading through a gown.** Never thread EVD CSF collection tubing through the sleeve of a patient's gown, which is usually done with a central venous line.

**Staff education.** Annual skills review to reinforce safe use of EVDs is required for those who typically manage the drains. Staff who infrequently encounter EVDs increases the risk of a misconnection error. While just identifying the risk is not enough to prevent a potential misconnection, all professional staff should be informed about EVDs, if used in the hospital, to raise awareness. Whenever possible, staff members who have been educated and are familiar with EVDs should stay with patients during procedures and be actively involved in the checking process to reduce the risk of wrong route drug administration.

**Recognize inadvertent intraventricular administration.** Educate providers and staff to recognize the signs and symptoms of accidental intraventricular administration (e.g., hypertension, anxiety, depressed mentation, aphasia, dysarthria, facial drooping) so they can manage the event promptly. When reading a cranial contrast-enhanced MRI, Lele et al. suggest that profound hyposensitivity throughout the ventricular system and subarachnoid spaces as well as susceptibility artifact along the margins of the ventricles should be a signal that inadvertent intraventricular contrast administration has occurred.[2] Evaluating the EVD collection bag can also confirm the presence of contrast media.

## Intrahospital Transport/Transfer of Patients with an EVD

**Transport/transfer policy and procedure.** Establish a policy and procedure for intrahospital transport/transfer of patients with an EVD. At a minimum, include guidance describing the transport of patients with an open or closed CSF collection system (if closed, ensure clamping at both the proximal port on the EVD and distal port on the CSF collection system); determine head-of-bed status during transport and leveling of the EVD at the external auditory meatus (ear); use a dedicated, clearly labeled, IV pole for the EVD mount; require patient monitoring during transport; troubleshoot for typical problems like kinked tubing; and the management of intracranial hypertension, including the medications needed to treat this crisis.[2,3] A pre-transport screening checklist may prove to be helpful.

**Accompany patients.** A patient with an EVD requires monitoring during transport by a trained professional (nurse, physician) familiar with EVDs and the management of intracranial hypertension. Monitoring might include capnography and arterial, intracranial, and cerebral infusion pressure readings. The transporting practitioner also must confirm the availability of medications needed to treat intracranial hypertension should the need arise during transport.

**Provide a verbal handoff report.** The trained professional who accompanies the patient during transport should, at a minimum, provide a verbal handoff to the receiving practitioner. The receiving practitioner's scope of practice and familiarity with EVDs should be considered, and enough guidance should be provided to ensure the patient's safety. For example, the trained professional accompanying a patient to the radiology suite for an invasive procedure or contrast-enhanced MRI should speak directly with the technologist or radiology practitioner(s) conducting the study, point out the EVD and the need to avoid all tubing connections and injections into any EVD access port, and identify which specific IV line and port to use if an IV injection is or might be required. A standardized handoff tool, such as a checklist, should be considered to guide the handoff process.

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Not only does this situation create a financial issue, but it also causes a patient safety issue since scanning the medication does not ensure product verification. The issue is also problematic because the dose may be repeated if another practitioner thought it had not been administered, or since the healthcare team might make incorrect decisions about patient care based on an inaccurate medication administration history.

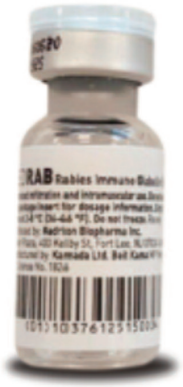

**Figure 1.** Edges of the Kedrab barcode are not captured by a barcode scanner.

The vial is packaged in a carton that has a scannable barcode, but nurses usually discard this after removing the vial, so it is no longer available at the bedside during administration. While not ideal, for now, this pharmacy is asking nurses to hold on to the carton to scan its barcode at the bedside before administering the product, rather than scanning the barcode on the vial. At a minimum, nurses should manually document administration on the MAR if the carton has already been discarded. The pharmacy will be reviewing reports daily to verify that the medication was charted as given, as well as billed appropriately.

## Special Announcement

### Survey on disrespectful behavior

Submit your responses to our survey on **disrespectful behavior in healthcare** by **November 19, 2021**. Disrespectful behavior is defined as: any overt or covert interaction (or lack of interaction) between healthcare professionals that may result in either an intended or unintended reluctance to speak up about concerns, question patient care, or share an opinion on a subject. Please visit: www.ismp.org/ext/761.

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## Safety Steps Prior to Injection

**Perform a universal "time out."** Perform a "time out" with all procedural staff in the room to identify the patient, the procedure being done, the access port for IV injections, and other IV lines or drains also attached to the patient.

**Trace the lines.** All of these cases highlight the importance of confirming the route of administration by tracing all access lines and injection ports to their origin (insertion site into the patient) prior to administration. Label all lines placed during a procedure.

**Aspirate blood.** If appropriate, use a syringe to aspirate blood prior to injection to verify intravascular placement of a line being used for IV administration. If the syringe has been accidentally attached to an EVD port, the aspirate (CSF) would most likely be a clear yellow color (xanthochromic), tea colored, or pink, but not frank blood.[2,3]

## ISO and EVD Manufacturer Recommendations

**ISO standards and design changes.** It is our hope that these rare but serious events will lead to the use of the ISO medical device standard for neuraxial connectors, NRFit. These are unique and cannot be attached to other medical connectors, including Luer lock syringes/tubing. In our opinion, NRFit compatibility of EVDs, CSF collection system tubing, and any associated stopcocks or ports should be accomplished as soon as possible. We have made this suggestion to the Global Enteral Device Supplier Association (GEDSA), which represents companies implementing ENFit, also an ISO standard. ENFit prevents misconnections between gastrointestinal tubes and catheters and Luer connectors. We also strongly encourage EVD collection system manufacturers to design their products so the tubing does not resemble IV tubing.

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**Report medication and vaccine errors to ISMP:** Please call 1-800-FAIL-SAF(E), or visit www.ismp.org/report-medication-error. ISMP guarantees the confidentiality of information received and respects the reporters' wishes regarding the level of detail included in publications.

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## Meet our 2021-2022 Fellows

**Sunny Ro, MS, PharmD**, is the **2021-2022 ISMP International Medication Safety Management Fellow**, supported by Novartis, Name Creation & Regulatory Strategy. She completed her Doctor of Pharmacy degree at Temple University School of Pharmacy and PGY1 pharmacy practice residency at Thomas Jefferson University Hospital in Philadelphia, PA. Prior to becoming a pharmacist, Sunny was a special education math teacher in Baltimore, MD. Through ISMP she hopes to unite, connect, and educate the world on medication safety.

**Emily Holcomb, PharmD, BCPS**, is the **2021-2022 ISMP Safe Medication Management Fellow**, supported by the US Army. Emily is an active-duty US Army Officer and has most recently worked as the Deputy Chief, Pharmacy Services at Tripler Army Medical Center in Honolulu, HI. She received her Doctor of Pharmacy from Pacific University, in Forest Grove, OR. Prior to her appointment in Honolulu, she spent several years in clinical and managerial roles in other US military health facilities, where she developed an interest in medication safety.

**Wykeem Parker, BS, PharmD**, is the **2021-2022 FDA/ISMP Safe Medication Management Fellow**. He completed his Bachelor of Science in Biology and Doctor of Pharmacy degrees at Temple University in Philadelphia, PA. Prior to the fellowship, Wykeem practiced as a clinical pharmacist at the Hospital of the University of Pennsylvania in Philadelphia, PA. During pharmacy school, he completed a medication safety track and rotation with ISMP, where he developed a passion for safety and quality improvement.

**Samuel Suen, PharmD**, is the **2021-2022 FDA/ISMP Safe Medication Management Fellow**. He completed his Doctor of Pharmacy at the University of Maryland School of Pharmacy in Baltimore, MD, and completed a PGY1 pharmacy practice residency at MedStar Georgetown University Hospital in Washington, DC. Sam's passion for medication safety emerged while serving on a hospital interdisciplinary medication safety committee.


## Register for the Virtual Cheers Awards Celebration!

Please join ISMP on Tuesday evening, **December 7, 2021**, at 6:00 p.m. ET, for our **virtual** 24th Annual Cheers Awards. We will be honoring a group of healthcare leaders who have left their footprint on medication safety by developing best practices and programs that prevent medication errors and protect patients. To register for the free event, please visit: www.ismp.org/node/25790.

## Help Support ISMP During Our Only Fundraising Event!

You can honor this year's Cheers Awards winners by attending the virtual awards celebration, purchasing raffle tickets for a variety of high-end prizes, and/or making a donation. With your support, ISMP can continue on our path to promote safe medication use in all healthcare settings. To purchase raffle tickets, please visit: www.ismp.org/ext/790. To make a donation, please visit: www.ismp.org/node/25784.

## ISMP Virtual Activities During the 2021 ASHP Midyear Clinical Meeting

### Workshop (preregistration required)

☐ **Thursday, December 2 and Friday, December 3**

**ISMP Medication Safety Intensive (MSI) Workshop**
To register, visit: www.ismp.org/node/25541

### Symposia (preregistration required)

☐ **Tuesday, December 7**

**A Call to Action: Dedicated Medication Safety Transformation in the Perioperative Setting**
1:00 p.m. – 2:30 p.m. ET
To register, visit: www.ismp.org/node/26682

☐ **Wednesday, December 8**

**Raising the Bar on Sterile Compounding Safety**
1:00 p.m. – 2:30 p.m. ET
To register, visit: www.ismp.org/node/26726

### ASHP Educational Sessions with ISMP Speakers

☐ **Wednesday, December 8**

**ISMP Medication Safety Update 2021**
3:00 p.m. – 4:30 p.m. ET

☐ **On-Demand**

**Don't Overlook the Essentials of Ambulatory Pump Safety**

## Keynote Speaker and Lifetime Achievement Award Winner:

**Patricia Kienle, RPh, MPA, BCSCP, FASHP**

Patricia Kienle is one of the nation's foremost experts on medication management and safety, as well as on accreditation and regulatory issues. She has more than 45 years of experience helping healthcare administrators develop and execute comprehensive medication management programs in acute and non-acute care environments, and currently is Director of Accreditation and Medication Safety for Cardinal Health. Ms. Kienle has completed an executive fellowship in patient safety at Virginia Commonwealth University and frequently offers her expertise on areas that impact error prevention, including serving as an educational resource for USP's <797> sterile compounding standards. She is a former board member of ISMP and the American Society of Health-System Pharmacists (ASHP), and has served as the president of the Pennsylvania Society of Hospital Pharmacists. She has earned numerous state and national awards, including the 2014 ASHP Award for Distinguished Pharmacy Leadership.